Gilead Sciences Begins Phase II Human Testing of Oral PMPA for Treatment of HIV; Combinations Including Hydroxyurea to be Evaluated

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Gilead Sciences, Inc. (NASDAQ:GILD) announced today that it has begun enrolling patients in a Phase II study to evaluate the oral prodrug of PMPA (oral PMPA) for the potential treatment of human immunodeficiency virus (HIV) infection. Study Design

The Phase II study (GS 902) is a double-blind, placebo-controlled, dose-ranging trial that will evaluate the safety and antiviral activity of oral PMPA as a component of combination antiretroviral regimens in treatment-experienced patients. The study is designed to enroll up to 175 patients infected with HIV who have HIV RNA levels greater than or equal to 400 copies/mL and less than or equal to 50,000 copies/mL and who have maintained a stable antiretroviral regimen (comprised of not more than three antiretroviral agents) for the eight weeks prior to enrollment.

Patients will be randomized to add one of three doses of oral PMPA or placebo to their existing regimens. Following randomization, patients will be encouraged to maintain their antiretroviral regimen for at least four weeks. After four weeks they may continue to receive blinded dosing of oral PMPA and be able to change their background antiretroviral therapy as necessary. After 24 weeks, patients who were randomly assigned to receive placebo will be eligible to crossover to open-label active oral PMPA for the remainder of the 48 week study period. The study will be conducted at approximately twenty clinical research centers in the United States.

Additionally, a Phase I/II study is currently ongoing in the United States to evaluate oral PMPA in combination with hydroxyurea, a compound that has been demonstrated to enhance the antiretroviral activity of PMPA in vitro. This trial is enrolling HIV-infected patients with CD4 counts greater than or equal to 200 cells/mm3 and HIV RNA greater than or equal to 10,000 copies/mL. Oral PMPA Phase I/II Study Results

Data from a previous Phase I/II study demonstrated that as monotherapy, oral PMPA at doses of 300 mg, 150 mg or 75 mg reduced plasma HIV RNA levels from baseline after 28 days of once-daily dosing by a median of 1.22 log(10), 0.44 log(10) and 0.32 log(10), respectively, compared to a median decrease of 0.06 log(10) in the placebo group. A total of 36 HIV-infected patients enrolled in the study, with more than half of the patients having previously received anti-HIV drug therapy.

In this Phase I/II study, treatment with oral PMPA was well tolerated. Reported adverse events (Grade 3 or greater) included reversible elevations in creatine kinase (18% in the treatment group vs. 13% in the placebo group) and serum transaminases (11% in the treatment group vs. 0% in the placebo group). Creatine kinase is a laboratory marker of muscle metabolism that can become elevated in relation to exercise. Information on Enrolling in Gilead's Clinical Trials for the Treatment of HIV

In addition to PMPA, Gilead is developing PREVEON® (adefovir dipivoxil) for the potential treatment of HIV infection. PREVEON is being tested in a variety of Phase II/III clinical trials in North America, Europe and Australia and is available in the United States through an Expanded Access Program for patients with limited treatment options. Data from pivotal clinical trials demonstrate that treatment with PREVEON has been associated with durable anti-HIV activity, including in patients infected with strains of HIV resistant to common nucleoside therapies. To date, side effects observed include changes in laboratory markers of renal function, dose-related gastrointestinal effects, including nausea and loss of appetite, and increases in liver transaminases.

Patients and physicians who would like more information about enrollment in the clinical trials of PMPA or PREVEON may call the AIDS Clinical Trials Information System (ACTIS) at 1-800-TRIALS-A or Gilead Sciences Medical Information at 1-800-GILEAD-5 (1-800-445-3235).

Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated treatment solutions for patients and the people who care for them. The Company discovers, develops and commercializes proprietary therapeutics for important viral diseases, including a currently marketed product, VISTIDE® (cidofovir injection), for the treatment of CMV retinitis, a sight-threatening viral infection in patients with AIDS. In addition, the Company is developing products to treat diseases caused by HIV, hepatitis B virus and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.

Note to Editors: VISTIDE is a registered trademark and PREVEON is a trademark of Gilead Sciences, Inc. To receive more information, please visit the Gilead Web site at www.gilead.com or call Corporate Communications at 1-800-GILEAD-5 (1-800-445-3235).

The numbers 10 in parentheses (10) in the fifth graf are subscript numerals. Gilead Sciences is an independent biopharmaceutical company that seeks to provide accelerated treatment solutions for patients and the people who care for them. The Company discovers, develops and commercializes proprietary therapeutics for important viral diseases, including a currently marketed product for the treatment of CMV retinitis, a sight-threatening viral infection in patients with AIDS. In addition, the Company is developing products to treat diseases caused by HIV, hepatitis B virus and influenza virus. Gilead common stock is traded on The Nasdaq Stock Market under the symbol GILD.

This press release contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, concerning the timing of potential registration filings for GS 4104 and presentation of clinical data at scientific conferences. Such statements are subject to certain risks and uncertainties, particularly those inherent in the process of discovering, developing and commercializing drugs that are safe and effective as human therapeutics. Actual results could differ materially from those projected in this release. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 1997 on file with the U.S. Securities and Exchange Commission, copies of which are available from Gilead.